



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA-2008-D-0610]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance on “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic.”

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2008-D-0610 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and

Dietary Supplements During an Influenza Pandemic

OMB Control Number 0910-0701--Extension

This information collection supports the above captioned Agency guidance. The guidance includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) maintain documentation of the conditions that prevent them from meeting normal reporting requirements; (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when

the conditions exist and when the reporting process is restored; and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the guidance, we estimate that approximately 5,000 firms will add the following to their COOP: (1) instructions for reporting adverse events and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records.

We therefore estimate the burden of the collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Type of Reporting	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Notify FDA when normal reporting is not feasible	500	1	500	8	4,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

Type of Recordkeeping	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Hours Per Record	Total Hours
Add adverse event reporting plan to COOP	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored	500	1	500	8	4,000
Total					258,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our experience with the information collection we have retained our current burden estimate of 258,000 hours annually.

Dated: October 26, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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